

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INTERNATIONAL APPL. NO. : PCT/GB97/00971
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APPLICANTS : ANDREW WILLIAM HEATH
TITLE OF INVENTION : T-CELL DEPENDENT VACCINE AND
THE CELL SURFACE RECEPTOR CD28
ATTORNEY'S DOCKET NO. : 2257-1-002

PRELIMINARY AMENDMENT

BOX PCT
ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

Sir:

Prior to calculating the fees for the filing of the above-identified Application, please make the following amendments to the CURRENT CLAIMS that were filed prior to the International Preliminary Examination Report which are enclosed herein.

IN THE CLAIMS:

Please amend the claims as follows:

3. (Amended) A vaccine according to Claim 1 [or 2] wherein said antigen is a protein.
4. (Amended) A vaccine according to Claim 1 [Claims 1-3] wherein said antigen and said adjuvant are cross-linked theretogether.
5. (Amended) A vaccine according to Claim 1 [Claims 1-4] wherein said vaccine is composed of said antigen and said adjuvant which are not physically co-joined.

6. (Amended) A vaccine according to Claim 1 [Claims 1-5] wherein said adjuvant is recombinantly manufactured.
8. (Amended) A vaccine according to Claim 1 [Claims 1-7] wherein said vaccine comprises an immunostimulating composition adapted to elicit an enhanced cytotoxic T-cell response.
10. (Amended) A vaccine according to Claim 1 [Claims 1-9] wherein said vaccine comprises[,] liposomes, biodegradable microspheres or an emulsion of antigen and adjuvant in oil.
12. (Amended) A method for the manufacture of a vaccine according to Claim 11 wherein said antigen and adjuvant [, is/] are recombinantly manufactured and are co-joined to produce a chimeric fusion protein.
13. (Amended) A method according to Claim 11 [or 12] wherein said antigen and adjuvant are cross-linked theretogether.
15. (Amended) A system according to Claim 14 wherein said system is adapted so that said cell secretes said antigen and/or adjuvant, and wherein when [in the instance where] both are secreted they are secreted either singularly or as a co-joined fusion protein.
18. (Amended) An isolated DNA molecule encoding [either or both] said antigen [and/or said adjuvant according to Claims 1-10] of Claim 1.

Please add the following new claims:

- 26. An isolated DNA molecule encoding said adjuvant of Claim 1.

27. An isolated DNA molecule encoding the recombinant fusion protein of Claim 7.
28. A vaccine according to Claim 2 wherein said soluble antigen is a protein.
29. A vaccine according to Claim 28 wherein said protein and said adjuvant are cross-linked theretogether.
30. A method according to Claim 11 wherein said antigen and said adjuvant are cross-linked theretogether.--


REMARKS

Claims 1-8, 9-15, 18, and 26-30 are presented for consideration.

Claims 3-6, 8, 10, 12, 13, 15, and 18 have been amended and Claims 26-30 have been submitted to place the Claims of the instant Application into conformity with U.S. claim practice and to thereby expedite the examination thereof. No new matter has been entered.

Favorable consideration and an early action on the merits are believed to be in order, and are courteously solicited.

Respectfully submitted,


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CURRENT CLAIMS

1. A vaccine suitable for enhancing and/or modulating T-cell dependent immunity comprising a T-cell dependent antigen, or part thereof, and an associated adjuvant, B7.1 and/or B7.2, or an active binding fragment thereof, which is adapted to stimulate a T-cell lymphocyte via the cell surface receptor CD28.
2. A vaccine according to Claim 1 wherein said antigen is a soluble antigen.
3. A vaccine according to Claim 1 or 2 wherein said antigen is a protein.
4. A vaccine according to Claims 1-3 wherein said antigen and said adjuvant are cross-linked theretogether.
5. A vaccine according to Claims 1-4 wherein said vaccine is composed of said antigen and said adjuvant which are not physically co-joined.
6. A vaccine according to Claims 1-5 wherein said adjuvant is recombinantly manufactured.
7. A vaccine according to Claim 6 wherein said antigen and said adjuvant comprise a recombinant fusion protein.
8. A vaccine according to Claims 1-7 wherein said vaccine comprises an immunostimulating composition adapted to elicit an enhanced cytotoxic T-cell response.
10. A vaccine according to Claims 1-9 wherein said vaccine comprises, liposomes, biodegradable microspheres or an emulsion of antigen and adjuvant in oil.

11. A method for the manufacture of a vaccine capable of eliciting a T-cell dependent immune response comprising selecting a suitable T-cell dependent antigen, or part thereof, and combining said antigen, and an adjuvant, B7.1 and/or B7.2, or an active binding fragment thereof, whereby said vaccine is adapted to stimulate a T-cell specific response by stimulation of a T-cell receptor CD28.
12. A method for the manufacture of a vaccine according to Claim 11 wherein said antigen and adjuvant, is/are recombinantly manufactured and are co-joined to produce a chimeric fusion protein.
13. A method according to Claim 11 or 12 wherein said antigen and adjuvant are cross-linked theretogether.
14. A system for use in the production of a vaccine capable of eliciting a T-cell dependent immune response wherein said system comprises a cell expressing a selected T-cell dependant antigen, or part thereof, and an adjuvant, B7.1 and/or B7.2, or an active binding fragment thereof.
15. A system according to Claim 14 wherein said system is adapted so that said cell secretes said antigen and/or adjuvant, and in the instance where both are secreted they are secreted either singularly or as a co-joined fusion protein.
18. An isolated DNA molecule encoding either or both said antigen and/or said adjuvant according to Claims 1-10.